

REMARKS

Amendments to the Specification

The application is amended herein to recite "Figures 22A and B" and "Figures 24A and B" at page 60. The drawings as filed show parts A and B of each figure and these amendments do not introduce new matter.

Rejections and Objections

Claims 47, 48 and 58-60 are pending in the present application. The Examiner has raised several objections and rejections. For clarity, these objections and rejections are listed below in the order in which they are addressed herein.

- I. The disclosure is objected to for informalities regarding the descriptions of Figures 22 and 24;
- II. Claims 47, 48 and 58-60 are rejected under 35 U.S.C. §101 as allegedly lacking a substantial utility; and
- III. Claims 47, 48 and 58-60 are rejected under 35 U.S.C. §112, first paragraph for allegedly failing to teach one of skill in the art how to use the invention.

I. The Examiner has asserted that references to Figures 22 and 24 on page 60 should recite "Figure 22A and B" and "Figure 24A and B," respectively. For business reasons and without acquiescing to the Examiner's objections, and reserving the right to prosecute applications having the original language in the future, the present application is amended herein to recite "Figures 22A and B" and "Figures 24A and B" at page 60. Applicants submit that grounds for these objections have been addressed and respectfully request that these objections to the specification be removed.

II. Claims 47, 48 and 58-60 are rejected under 35 U.S.C. §101 as allegedly lacking any specific or substantial asserted utility, or well established utility. Applicants respectfully disagree, as Applicants have asserted specific utility for the compositions of

the present invention. As indicated in the specification, the claimed compositions are novel enzymes designed for direct detection, characterization and quantitation of nucleic acids, particularly RNA (page 22, lines 29-30). As further indicated in the Description of the Invention at page 125, lines 14-19, the enzymes of the present invention are particularly useful in the performance of detection assays based on the cleavage of a structure that comprises an RNA strand. The INVADER invasive cleavage reaction is indicated to be one such assay (page 124 at lines 25-27).

The polypeptide of SEQ ID: 2857 is specifically identified as an enzyme having improved RNA-dependent 5' nuclease activity. See, for example, the description of the construction of the enzyme at page 273, lines 11-17. The description of this enzyme is part of Example 9, which begins on page 220 at line 28 and which is entitled "Additional Enzymes having Improved RNA-dependent 5' nuclease activity." Examples of "improved" activity of the claimed enzymes include but are not limited to improved performance in detection assay, as described at page 23 lines 12-20:

"The improved performance in a detection assay may arise from any one of, or a combination of several improved features. For example, in one embodiment, the enzyme of the present invention may have an improved rate of cleavage (k_{cat}) on a specific targeted structure, such that a larger amount of a cleavage product may be produced in a given time span. In another embodiment, the enzyme of the present invention may have a reduced activity or rate in the cleavage of inappropriate or non-specific structures. "

The compositions presently claimed have at least the specific utility asserted for all of the novel enzymes of the invention: *i.e.*, they are useful in the "performance of detection assays based on the cleavage of a structure that comprises an RNA strand," (page 125, lines 16-19.)

As described above, Applicants have indeed asserted substantial and specific utilities for the presently claimed invention. As such, Applicants submit that the invention as claimed meets the requirements of 35 U.S.C. §101 and respectfully request that these rejections be removed.


III. Claims 47-48 are rejected under 35 U.S.C. §112, first paragraph. In particular the Examiner alleges that, in view of the alleged lack of substantial asserted utility discussed above, one skilled in the art would not know how to use the claimed invention.

Applicants disagree. As discussed above, Applicants have clearly asserted substantial and specific utility for the improved cleavage enzymes of the present invention. Further, the specification provides ample guidance for using the claimed invention. For example, Example 19, beginning on page 297 at line 17, provides detailed procedures for use of the enzymes of the invention (referred to generally as CLEAVASE enzymes), in the detection and quantitation of RNA such as mRNA using cleavage assays. As such, one of skill in the art, upon consideration of the specification, would know how to use the claimed invention and Applicants therefore respectfully request that these rejections be removed.

CONCLUSION

For the reasons set forth above, it is respectfully submitted that all rejections and objections should be removed and Applicants' claims should be passed to allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourages the Examiner to call the undersigned collect at (608) 218-6900.

Dated: 7/6/2005



Mary Ann D. Brown
Registration No. 42,363

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105
608.218.6900